

LISTING OF THE CLAIMS

No amendments to the claims are being made with the present Amendment. This listing of the pending claims is provided solely for the convenience of the Examiner.

Listing of Claims:

1-15. (Canceled).

16. (Previously presented) A sustained release preparation comprising a combination of first microcapsules which gradually release a GnRH agonist or a salt thereof for 5 months or longer, and second microcapsules which gradually release a GnRH agonist or a salt thereof for shorter than 5 months so that blood concentration of the GnRH agonist within one week after administration is about 2 ng/mL or higher, wherein:

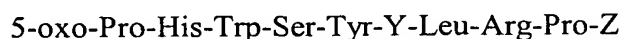
(a) the first microcapsules comprise:

- (i) a GnRH agonist or a salt thereof, and
- (ii) a lactic acid polymer having a weight-average molecular weight of about 18,000 to about 30,000; and

(b) the second microcapsules comprise:

- (i) a GnRH agonist or a salt thereof, and
- (ii) a lactic acid-glycolic acid polymer (75/25 (mol %)) having a weight-average molecular weight of 3,000 to about 12,000, or a lactic acid polymer having a weight-average molecular weight of about 13,000 to about 18,000.

17. (Previously presented) The preparation according to claim 16, wherein the GnRH agonist or a salt thereof is a peptide represented by the formula of SEQ ID NO: 1:



wherein Y represents a residue selected from DLeu, DAla, DTrp, DSer (tBu), D2Nal and DHis (ImBzl), and Z represents NH-C₂H₅ or Gly-NH₂

or a salt thereof.

18. (Previously presented) The preparation according to claim 16, wherein the GnRH agonist or a salt thereof is an acetate of a peptide of the formula of SEQ ID NO: 2:

5-oxo-Pro-His-Trp-Ser-Tyr-Dleu-Leu-Arg-Pro-NH-C₂H₅

19. (Canceled)
20. (Previously presented) The preparation according to claim 16, wherein the long term is 5 months or longer and 8 months or shorter, and the short term is 1 week or longer and shorter than 5 months.
21. (Canceled)
22. (Previously presented) The preparation according to claim 16, wherein the ratio of first microcapsules to second microcapsules is from 5:1 to 20:1 expressed as weight ratios of the GnRH agonist or a salt thereof.
23. (Canceled)
24. (Canceled)
25. (Previously presented) The sustained-release preparation according to claim 16, which gradually releases a substantially constant amount of a GnRH agonist or a salt thereof for 5 months or longer.
26. (Canceled)
27. (Previously presented) A composition comprising:
 - (a) a pharmaceutically effective amount for preventing or treating prostate cancer, prostatomegaly, endometriosis, hysteromyoma, metrofibroma, precocious puberty, dysmenorrhea or breast cancer, or for contraception of the sustained-release preparation according to claim 16, and
 - (b) a pharmaceutically acceptable excipient.
28. (Previously presented) A process for producing the sustained-release preparation according to claim 16, which comprises mixing the first and second microcapsules.

29. (Previously presented) A method comprising administering an effective amount for preventing or treating prostate cancer, prostatomegaly, endometriosis, hysteromyoma, metrofibroma, precocious puberty, dysmenorrhea or breast cancer, or preventing conception of the sustained-release preparation according to claim 16 to a mammal in need thereof.

30. (Previously presented) The preparation according to claim 16, wherein:

(a) the first microcapsules comprise:

(i) a GnRH agonist or a salt thereof, and

(ii) a lactic acid polymer having a weight-average molecular weight of about 21400; and

(b) the second microcapsules:

(1) comprise (i) a GnRH agonist or a salt thereof, and (ii) a lactic acid-glycolic acid polymer (75/25 (mol%)) having a weight-average molecular weight of about 10400, or

(2) comprise (i) a GnRH agonist or a salt thereof, and (ii) a lactic acid polymer having a weight-average molecular weight of about 14200.